K120709

APR - 6 2012

NDS SURGICAL · IMAGING

510(K) SUMMARY

A. Manufacturer:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Jim Leng Regulatory Engineer/NDS Surgical Imaging, LLC
C. Date of Preparation:	February 15, 2012
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Picture Archiving Communication System
F. Common Name:	System, Image Processing, Radiological
G. Proprietary Name:	The Dome® GX4MP Color Monitor
H. Classification Number:	21 CFR 892.2050
I Product Code:	LLZ
J. Substantial Equivalence:	Predicate K060136 PLANAR DOME DIGITAL FLATPANEL DISPLAY SYSTEM, Model E4c
K. Device Description:	The Dome® GX4MP Color Monitor is a 30-inch 4 mega-pixel Color flat-panel AMLCD-TFT monitor for use with IBM PC or PC compatible computers for widescreen imaging. The combination of high resolution and high contrast ratio allow the viewing of color and grayscale images simultaneously.
L. Intended Use:	The Dome® GX4MP Color Monitor is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.
M. Technological Characteristics:	Bezel-free framing of 4 megapixels of data is presented in a landscape resolution of 2560 x 1600 pixels. Gamma correction is achieved on this true color display from a palette of 1786 near-gray values.

The integrated Dome RightLight Controller monitors and stabilizes backlight luminance. The display unit includes a PCI Express graphics board to support the required dual-link connectivity for the display.

Substantial Equivalence Comparison Chart

	Prior approved device.	New device.
Product Model Name	Dome E4c	Dome GX4MP
Intended Use	To be used in displaying and viewing medical images for review and analysis by trained medical practitioners.	Unchanged.
Display characteristics	4MP 2560x1600 pixel display 16 million colors 1786 shades of near-gray values Factory DICOM calibrated 370 cd/m^2 IPS technology 700:1 contrast ratio 170 degree viewing angle	Unchanged.
Power Supply	External IEC/EN 60601-1 power supply.	Internal IEC/EN 60950 power supply.
Location for Use	Radiology reading room. Not intended or marketed for near-patient use.	Unchanged.
Enclosure	Laser-cut sheet metal back. Metal and glass bezel.	Molded plastic back and bezel. Integrated USB hub.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jim Leng
Regulatory Engineer
NDS Surgical Imaging, LLC
5750 Hellyer Avenue
SAN JOSE CA 95138

APR - 6 2012

Re: K120709
Trade/Device Name: The Dome® GX4MP Color Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 28, 2012
Received: March 8, 2012

Dear Mr. Leng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(If known)

Device Name: The Dome® GX4MP Color Monitor

Indications for Use The Dome® GX4MP Color Monitor is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120709

Prescription Use __X____
(Per 21 CFR 801.109)

OR Over-The-Counter Use_____